

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:

Thomas BACKENFELD et al.

Serial No.: 10/022,845

Examiner: Patrick T. Lewis

Filed: December 20, 2001

Group Art Unit: 1623

Title: COMPOSITIONS OF ESTROGEN-CYCLODEXTRIN COMPLEXES

**INFORMATION DISCLOSURE STATEMENT  
UNDER 37 C.F.R. §§ 1.56, 1.97 AND 1.98**

Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

Sir:

This information disclosure statement is made in accordance with 37 C.F.R. §§ 1.56, 1.97 and 1.98 as follows:

**TIMING AND FEES**

- ☒ Under 37 C.F.R. § 1.97(b), no fee or statement is required for filing this information disclosure statement is filed:
- ☐ within three months of the filing date of a national application other than a CPA under § 1.53(d);
  - ☐ within three months of the actual filing date of the national phase of a PCT application; OR
  - ☒ before the mailing of a first substantive office action (including after filing of an RCE).
- ☐ Under 37 C.F.R. § 1.97(c), this information disclosure statement is filed after the periods specified in 37 C.F.R. § 1.97(b), but before the mailing date of:
- ☐ a final rejection under 37 C.F.R. § 1.113;
  - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - ☐ a notice of allowance under 37 C.F.R. § 1.311; and

is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) set out below; OR
- ☐ a check covering the fee of \$180.00 under 37 C.F.R. § 1.17(p).
- ☐ Under 37 C.F.R. § 1.97(d), this information disclosure statement is filed after the mailing date of the following actions which have not been withdrawn:
  - ☐ a final action under 37 C.F.R. § 1.113;
  - ☐ termination of prosecution, e.g. Ex Parte Quayle, M.P.E.P § 609(B)(2); OR
  - ☐ a notice of allowance under 37 C.F.R. § 1.311;

AND is filed on or before payment of the issue fee; AND is accompanied by:

- ☐ the statement as specified in 37 C.F.R. § 1.97(e) as set forth below, and the fee of \$180.00 under 37 C.F.R. § 1.17(p).

**STATEMENTS UNDER 37 C.F.R. 1.97(e)**

- ☐ Each item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application having a mailing date not more than three months prior to the filing date of this information disclosure statement; or
- ☐ No item of information contained in this information disclosure statement was cited in a communication from a foreign patent office in a counterpart foreign application, and to the knowledge of the undersigned attorney after making reasonable inquiry, no item of information contained in this information disclosure statement was known to any individual designated in 37 C.F.R. § 1.56(c) more than three months prior to the filing date of the information disclosure statement.

**CITED MATERIALS**

- ☐ Copies of materials listed but not attached were cited in benefit (35 U.S.C. § 120) ancestor application Serial No. \_\_\_\_\_, on Form 892 by the Examiner and/or Form 1449 by the applicant; see 37 C.F.R. § 1.98(d).
- ☐ Copies of materials listed but not attached were cited in an international search report dated \_\_\_\_\_.
- ☒ Copies of the materials listed are attached (except for the foregoing).

**NON-ENGLISH LANGUAGE REFERENCES**

- ☐ An English-language search report or equivalent paper from a foreign patent office is provided indicating the relevance of the cited reference(s).

☐ A foreign-language search report from a foreign patent office is provided, and pertinent parts are translated substantively below:

X = document of particular relevance when it is taken alone  
Y = document of particular relevance when it is combined with another such document  
A = document defining the general state of the art  
O = non-written disclosure  
P = intercalated document  
T = document cited to understand the theory or principle underlying the invention  
E = patent document which has the benefit of a date earlier than the filing date and which was published only on or after this filing date  
D = cited in the application  
L = cited for another reason  
& = publication of member of same patent family

☐ Translation of other relevant information on foreign search report

**OTHER INFORMATION**

WO 96/02277 corresponds to U.S. Patent No. 5,798,338, already of record; FR 1515187 corresponds to UK 2109381, cited herein; EP 398,460 contains an English-language abstract in the form of English-language claims, also it corresponds to Canadian Patent No. 2016780, an abstract thereof is cited here.

**PAYMENT OF FEES DUE (IF ANY):**

- ☐ A check for \$\_\_\_\_\_ covering the fee identified above is attached.
- ☐ Please charge to Deposit Account No. 13-3402 \$\_\_\_\_\_ for the fee identified above.
- ☒ The Commissioner is hereby authorized to charge or credit any overpayment to Deposit Account No. 13-3402, two copies of this paper are attached for this purpose.

Respectfully submitted,

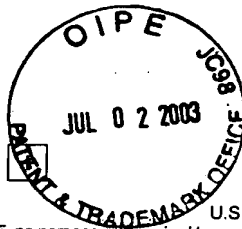
  
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Attorney Docket No.: PLOVIN-5

Date: July 2, 2003

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**INFORMATION DISCLOSURE  
STATEMENT BY APPLICANT**

(use as many sheets as necessary)

Sheet 1 of 1

Complete if Known

Application Number	10/022,845
Filing Date	December 20, 2001
First Named Inventor	Thomas BACKENFELD et al.
Group Art Unit	1623
Examiner Name	Patrick T. Lewis
Attorney Docket Number	PLOVIN-5

**U.S. PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	U.S. Patent Document		Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY
		Number	Kind Code <sup>2</sup> (if known)		
	A1	4,129,564		Weichert et al.	12-12-1978
	A2	4,877,774		Pitha et al.	10-31-1989
	A3	5,376,641		Ammeraal	12-27-1994
	A4	5,885,978		Yamada et al.	03-23-1999

**FOREIGN PATENT DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Foreign Patent Document			Name of Patentee or Applicant of Cited Document	Date of Publication of Cited Document MM-DD-YYYY	Pages, Columns, Lines, Where Relevant Passages or Relevant Figures Appear	T <sup>5</sup>
		Office <sup>3</sup>	Number <sup>4</sup>	Kind Code <sup>5</sup> (if known)				
	B1	CA	2016780		Wiechert et al.	07-11-2000		Abstract
	B2	EP	0398460	B1	Beier et al.	07-02-1997		
	B3	FR	2515187	A1	Stadler	10-26-1982		
	B4	UK	2109381		Gedeon et al.	06-02-1983		
	B5	WO	96/02277	A1	Backensfeld et al.	02-01-1996		

**NON PATENT LITERATURE DOCUMENTS**

Examiner Initials *	Cite No. <sup>1</sup>	Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published.	T <sup>2</sup>
	C1	ROLF KRATTENMACHER, "Drospirenone: pharmacology and pharmacokinetics of a unique progestogen," <i>Contraception</i> , Vol. 2, No. 1, July 2000, pp. 29-38	
	C2	P. NORMAN, "Drospirenone: Contraceptive, Hormone Replacement Therapy, Aldosterone Antagonist, Progestogen: 1, 2-Dihydrospirorenone, SH-470, ZK-30595," <i>Drugs of the Future</i> , Vol. 25, No. 12, December 2000, pp. 1247-1256	
	C3	K. UEKAMA et al., "Inclusion Complexations of Steroid Hormones With Cyclodextrins in Water and in Solid Phase," <i>International Journal of Pharmaceutics</i> , 10 (1982), pp. 1-15	
	C4	K. KRÁLOVÁ et al., "Interactions of $\beta$ -cyclodextrin with steroid compounds in aqueous solutions," <i>Pharmazie</i> , 1989, Vol. 44, No. 9, pp. 623-625	
	C5	W.A.J.J. HERMENS, "Delivery of hormones: some new concepts," <i>Pharm. Weekbl. Sci. Ed.</i> , 1992, Vol. 14, No. 4 A, pp. 253-257	
	C6	K. UEKAMA, "Cyclodextrin Inclusion Compounds: Effects on Stability and Bio-Pharmaceutical Properties," <i>Topics in Pharmaceutical Sciences</i> , Eds. D.D. Breimer and P. Speiser, 1987, Elsevier Science Publishers (Biomedical Division), pp. 181-194	
	C7	K. UEKAMA et al., "Cyclodextrin Drug Carrier Systems," <i>Chem. Rev.</i> , Vol. 98, No. 5, 1 July 1998, pp. 2045-2076	
	C8	PITHA et al., "Hydroxypropyl- $\beta$ -cyclodextrin: preparation and characterization; effects on solubility of drugs," <i>International Journal of Pharmaceutics</i> , 29(1), pp. 73-82 (1986)	

Examiner Signature	Date Considered
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\*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

<sup>1</sup> Unique citation designation number. <sup>2</sup> See attached Kinds of U.S. Patent Documents. <sup>3</sup> Enter Office that issued the document, by the two-letter code (WIPO Standard ST.3). <sup>4</sup> For Japanese patent documents, the indication of the year of the reign of the Emperor must precede the serial number of the patent document. <sup>5</sup> Kind of document by the appropriate symbols as indicated on the document under WIPO Standard ST. 16 if possible. <sup>6</sup> Applicant is to place a check mark here if English language Translation is attached.